

Remarks

The Examiner has rejected claims 1-23 under 35 U.S.C. §103(a) as being unpatentable over the combined disclosures of U.S. Patent No. 6,261,598 to Runge *et al.* and German Patent Application Publication No. DE4110087A1 to Woerwag *et al.*

U.S. Patent No. 6,261,598 to Runge has the main, active ingredient of the carotenoids beta carotene, lycopene and lutein, and lists benfotiamine in passing as one example within a laundry list of many potential adjunct ingredients which in total are present preferably in amount as little as 0.1 and up to 20%. The list of adjunct ingredients include other carotenoids (col. 2, lines 49), vitamins (col. 2, line 53), compounds with vitamin or coenzyme characteristics (col. 2, lines 62), polyunsaturated fatty acids (col. 2, line 65), garlic constituents (col. 3, line 1), allithiamines, such as benfotiamine (col. 3, lines 3-4), and glutathione (col. 3, line 3).

“To be anticipating, a prior art reference must disclose ‘each and every limitation of the claimed invention[,] . . . must be enabling[,] and [must] describe... [the]claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention.’ *In re Paulsen*, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed Cir. 1994).” *Helifix Ltd. V. Blok-Lok, Ltd.*, 208 F.3d 1339, 54 USPQ2d 1299 (Fed. Cir. 2000). The reference is no more enlightening as a basis for rejection under §103.

In Runge *et al.*, there is no discussion of the properties or effects of benfotiamine alone or when incorporated with any of these other listed ingredients. There is no disclosure or suggestion to use an effective amount of benfotiamine in a topical composition to improve skin condition, as in claimed by Applicant. Runge *et al.* patent does not teach benfotiamine for improving skin condition or treating skin damage. Likewise, Woerwag *et al.* fails to teach or suggest benfotiamine for such. Woerwag *et al.* discloses topical uses of benfotiamine for treatment of rheumatism and joint and neurological disorders. As discussed in the present application at benfotiamine is used in Germany to treat diabetic neuropathy, sciatica and other nerve conditions. (See Application p. 1, ¶3)

While method of administration of these treatments may be topical, they do not act to treat the symptoms of the nerve condition or infection which manifest on the skin, such as is the case with shingles which is caused by the varicella-zoster virus. Rather, the pharmaceutical in Woerwag *et al.* targets the underlying "affected part of the body" such as the virally infected nerve roots, the source of the symptoms (such as pain and rash) and not the symptoms themselves which may appear (rash) or be felt (pain) on the skin, for instance in the case of shingles.

The Examiner states that rheumatic disorders and shingles are conditions that are known in the art to cause skin damage. Applicant respectfully disagrees as these nerve disorders not skin disorders nor conditions that cause permanent skin damage. Shingles is a temporal symptom of a dormant viral infection of the nerves which at times may be reactivated. The disclosure in Woerwag *et al.* addresses treatment of nerve disorders, and while some of them may include topical symptoms, its use of benfotiamine addresses treatment and amelioration of the underlying viral infection. Woerwag *et al.* does not address benfotiamine for improvement of skin condition or treatment of skin damage.

The aforementioned remarks show claims 1-23 to be patentable and non-obvious over Runge *et al.* and Woerwag *et al.*, both alone and in combination. It is respectfully submitted that all of the claims in the application are in order for allowance, and early notice to that effect is respectfully requested.

Respectfully submitted,



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